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10/525,011

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Jari Natunen

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EXAMINER

GODDARD, LAURA B

ART UNIT

PAPER NUMBER

1642

NOTIFICATION DATE

DELIVERY MODE

06/12/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/525,011	Applicant(s) NATUNEN ET AL.	
	Examiner LAURA B. GODDARD	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 87-139 is/are pending in the application.
- 4a) Of the above claim(s) 87-131 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 132-139 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The Amendment filed March 9, 2009 in response to the Office Action of September 9, 2009, is acknowledged and has been entered. Claims 87-139 are pending. Claims 87-131 remain withdrawn. Previously pending claims 132, 133, and 138 have been amended. Claim 139 is new. Claims 132-139 are currently being examined.

Specification

2. The disclosure is objected to because of the following informalities: There are numerous typos throughout the specification, for example "malignat" on page 2, line 4; "Hwever" on page 3, line 19; "or or" on page 39, line 20, just to point out a few. Appropriate correction is required.

NEW REJECTIONS

(based on new considerations)

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 138 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 138 recites the limitation "said **modified**

Art Unit: 1642

galactosyltransferase" in reference to an engineered galactosyltransferase. There is insufficient antecedent basis for this limitation in the claim. Examiner suggests replacing the word "modified" with "engineered."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 132-139 are rejected under 35 U.S.C. 102(e) as being anticipated by US patent 7,265,084, DeFrees et al, filed April 9, 2003, issued September 4, 2007.

The claims are drawn to a composition comprising an enzyme substrate, capable of being transferred specifically to a surface of a pathogenic entity or malignant cell or tissue by a transferring enzyme making a covalent linkage between said enzyme substrate and an acceptor structure of said surface for use as a medicine, wherein the enzyme substrate is a 2-modified monosaccharide residue and the transferring enzyme is a glycosyltransferase or a transglycosylating enzyme; or the enzyme substrate is a modified monosaccharide residue and the transferring enzyme is a transglycosylating enzyme (claim 132), the composition according to claim 132, wherein said enzyme substrate is conjugated to an immunologically active substance and/or a toxic

Art Unit: 1642

substance (claim 133), the composition according to claim 132, wherein said enzyme substrate is a carbohydrate substance capable of being transferred specifically to the surface of a pathogenic entity or malignant cell or tissue by the transferring enzyme (claim 134), the composition according to claim 132, wherein said transferring enzyme is a glycosyl transsialidase or a transglycosylate enzyme (claim 135), the composition according to claim 132, wherein said enzyme substrate is a 2-modified monosaccharide residue (claim 136), the composition according to claim 132, wherein said enzyme substrate is according to the Formula UDP-GalN[-S-]-D, wherein S is an optional spacer group, D is a derivatizing group including molecular labels selected from the group consisting of biotin, a fluorescent molecule, a toxic agent, a prodrug or and a prodrug releasing substance (claim 137), the composition according to claim 132, wherein said enzyme substrate is transferred by a galactosyltransferase which is engineered to transfer effectively 2-modified monosaccharides or .by a natural GalNAc/GlcNAc-transferase with similar specificity with said modified galactosyltransferase from animals (claim 138), the composition according to claim 132, wherein the enzyme substrate is a 2-modified monosaccharide residue and the transferring enzyme is a glycosyltransferase enzyme (claim 139).

DeFrees et al teach the enzyme substrates UDP-galactose, UDP-glucose, UDP-mannose, UDP-galactosamine, and UDP-glucosamine, wherein the monosaccharide (galactose, glucose, mannose, galactosamine, or glucosamine) of the substrates has a 2-position modified by the addition of groups including: O, NH, S, CH₂, a linker, and a ligand of interest including: PEG, VEGF, FGF, protein, chondroitin,

Art Unit: 1642

keratan, integrins, and peptides (col. 11, lines 30-50; col. 172-col. 174, table 4). These substrates would encompass the formula UDP-GalN[-S-]-D or UDP-GalN-D as instantly claimed. DeFrees et al teach the peptides or proteins linked to the substrates can be therapeutic agents or agents for diagnosis including toxins, prodrugs, and radioisotopes (col. 45, lines 21-67; col. 143, line 44 to col. 42).

Although DeFrees et al does not specifically state these substrates are substrates for glycosyltransferases, transglycosylating enzymes, or a galactosyltransferase which is engineered to transfer effectively 2-modified monosaccharides by a natural GalNAc/GlcNAc-transferase with similar specificity with said engineered galactosyltransferase from animals, given the substrates of DeFrees et al are 2-modified monosaccharides and are UDP-monosaccharides, including UDP-galactose, the substrates taught by DeFrees et al appear to be the same substrates as instantly claimed, absent a showing of unobvious differences. Although DeFrees et al does not teach that the enzyme substrates are capable of being transferred specifically to a surface of a pathogenic entity or malignant cell or tissue by a transferring enzyme making a covalent linkage between said enzyme substrate and an acceptor structure of said surface, the substrates taught by DeFrees et al appear to be the same substrates as instantly claimed, absent a showing of unobvious differences. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different

from those taught by the prior art and to establish patentable differences. See In re Best 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 132-139 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bulter et al (Chemobiochem, 2001, 2:884-894) in view of US patent 7,265,084, DeFrees et al, filed April 9, 2003, issued September 4, 2007.

The claims are as set forth above.

Bulter et al teach a composition comprising an enzyme substrate, UDP-6-biotinyl-Gal or UDP-6-biotinyl-GalNAc, that is capable of being transferred by galactosyltransferase (a glycosyl transferase) to acceptor structures such as BSA-(GlcNAc)₁₇ and ovalbumin, and is a carbohydrate substance and a 2-modified monosaccharide (abstract, p. 885; Scheme 1 and 2; Figures 3-7). Bulter et al teach the selective transfer of labeled nucleotide sugars onto specific acceptor structures in a glycolipid or glycoprotein by glycosyltransferases, and teach that certain acceptor structures have tissue and cell-type specific expression associated with diseases such as cancer (p. 884, col. 1; p. 885, col. 1; p. 890, col. 1, paragraph 2; col. 2, last

Art Unit: 1642

paragraph). Bulter et al teach the production of nonradioactive-labeled (fluorescein) or tagged (biotin) UDP-Gal and UDP-GalNAc for diagnostic applications (p. 885, col. 1). Biotin can elicit an immune response, hence would be an immunologically active substance.

The reference does not specifically teach that the labeled UDP-GalNAc or UDP-Gal is capable of being transferred specifically to a surface of a pathogenic entity or malignant cell or tissue by a transferring enzyme making a covalent linkage between said enzyme substrate and an acceptor structure, or transferred by a galactosyltransferase which is engineered to transfer effectively 2-modified monosaccharides or by a natural GalNAc/GlcNAc-transferase with similar specificity with said modified galactosyltransferase from animals, however, the claimed enzyme substrate appears to be the same as the prior art enzyme substrate, absent a showing of unobvious differences. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See *In re Best* 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989)

The formula of the Bulter et al substrate is UDP-**GalNAc**-biotin (UDP-GalNAc-D) or UDP-**Gal**-biotin (UDP-Gal-D) but Bulter et al do not teach the formula UDP-**GalN**-D.

Art Unit: 1642

Bulter et al teach the biotin is attached at the 6-position but do not teach that it is attached at the 2-position of the monosaccharide galactose.

DeFrees et al teach the addition of R groups to UDP-galactose or UDP-galactosamine, wherein the R groups may be acetyl, a linker, or ligand such as PEG, FGF, VEGF, protein, integrins, or peptides (col. 173-174; Table 4), wherein the proteins or peptides can be diagnostic or therapeutic agents (col. 11, lines 30-50; col. 172-col. 174, table 4). DeFrees et al teach that UDP-galactose or UDP-galactosamine and be modified at the 2 position and that numerous methods are known and available for modifying galactose or N-acetylgalactosamine (col. 172-174; Table 4; col. 146, lines 22 to col. 148, line 15).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to and one would be motivated substitute GalN for Gal or GalNAc in the enzyme substrate taught by Bulter et al because DeFrees et al teach making an enzyme substrate with GalN and teach that methods are known and available for modifying galactose or N-acetylgalactosamine. One would be motivated to make the enzyme substrate for diagnostic or therapeutic purposes as taught by Bulter et al and DeFrees et al. One of ordinary skill in the art would have a reasonable expectation of success substituting GalN for Gal or GalNAc in the enzyme substrate taught by Bulter et al because DeFrees et al teach making the enzyme substrate with GalN and teach that methods are known and available for modifying galactose or N-acetylgalactosamine.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was attach the biotin, therapeutic, or diagnostic agent to the 2-position in place of the 6-position on the UDP-GalN-D taught by Bulter et al and DeFrees et al (the combined references) because DeFrees teach that therapeutic or diagnostic groups can be linked to the 2-position of a galactose or galactosamine. One would have been motivated to attach a biotin, therapeutic, or diagnostic agent to a 2-position of UDP-GalN in order to make a therapeutic or diagnostic agent as taught by the combined references. One of ordinary skill in the art would have a reasonable expectation of success attaching the biotin, therapeutic, or diagnostic group to the 2-position of UDP-GalN because Bulter demonstrate successful attachment of biotin to galactose and DeFrees teach that methods are known and available for modifying galactose.

Finally, the Supreme Court has determined, in *KSR International Co. v. Teleflex, Inc.*, 550 U.S. __, 82, USPQ2d 1385 (2007), that “.....[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results” (KSR, 550 U.S. at __, 82 USPQ2d at 1395). The court further found that “..... the conclusion that when a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious” (KSR, 550 U.S. at __, 82 USPQ2d at 1395-1396). Thus, when considering obviousness of a combination of known elements, the operative question is “whether the improvement is

Art Unit: 1642

more than the predictable use of prior art elements according to their established functions” ((KSR, 550 U.S. at_, 82 USPQ2d at 1396).

Given the above, applying the same logic to the instant process claims, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to substitute the GalN of UDP-GalN-D for the Gal or GalNAc in UDP-Gal-D or UDP-GalNAc-D taught by Bulter et al, because the prior art enzyme substrate of Bulter et al differs from the claimed enzyme substrate only by the substitution of the known monosaccharide GalN as claimed. Given that variations of Gal or GalNAc, such as GalN, were conventional and well known in the art at the time the invention was made wherein their functions were well known in the art, substitution of GalN for the Gal or GalNAc into the enzyme substrate of Bulter et al would have yielded predictable results to one of ordinary skill in the art at the time of the invention. The claims are obvious over the cited references because the results yielded would be no more than one would expect from such a substitution.

Given the above, applying the same logic to the instant process claims, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to move the biotin, drug, or therapeutic group from the 6-position to the 2-position of galactose or galactosamine monosaccharide taught by the combined references, because the prior art enzyme substrate differs from the claimed enzyme substrate only by the position of biotin, drug, or therapeutic group as claimed. Given that modifications of galactose or galactosamine and the attachment of biotin, drug, or therapeutic groups were conventional and well known in the art at the time the invention

Art Unit: 1642

was made, and their functions were well known in the art, substitution of a 2-position for the 6-position for the biotin, drug, or therapeutic groups into the enzyme substrate of the combined references would have yielded predictable results to one of ordinary skill in the art at the time of the invention. The claims are obvious over the cited references because the results yielded would be no more than one would expect from such a substitution.

Maintained Rejections

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

NOTE: The rejection below is maintained but adds new claim 139.

6. **Claims 132-136 and 138 remain rejected and new claim 139 are rejected** under 35 U.S.C. 102(b) as being anticipated by Bulter et al (Chemobiochem, 2001, 2:884-894) (see section 7 of the previous Office Action).

The claims are drawn to as set forth above.

It is noted that the preamble recitation of “for use as a medicine” as recited in claim 132 is merely suggestive of an intended use and is not given weight for purposes of comparing the claims with the prior art. The claims read on the active ingredients *per se*, which is a composition comprising an enzyme substrate, wherein the enzyme substrate is a 2-modified monosaccharide residue or the enzyme substrate is a modified monosaccharide residue (see MPEP 2111.02).

Bulter et al teach a composition comprising an enzyme substrate, UDP-6-biotinyl-Gal or UDP-6-biotinyl-GalNAc, that is capable of being transferred by galactosyltransferase (a glycosyl transferase) to acceptor structures such as BSA-(GlcNAc)₁₇ and ovalbumin, and is a carbohydrate substance and a 2-modified monosaccharide (abstract, p. 885; Scheme 1 and 2; Figures 3-7). Bulter et al teach the selective transfer of labeled nucleotide sugars onto specific acceptor structures in a glycolipid or glycoprotein by glycosyltransferases, and teach that certain acceptor structures have tissue and cell-type specific expression associated with diseases such as cancer (p. 884, col. 1; p. 885, col. 1; p. 890, col. 1, paragraph 2; col. 2, last paragraph). Bulter et al teach the production of nonradioactive-labeled (fluorescein) or tagged (biotin) UDP-Gal and UDP-GalNAc for diagnostic applications (p. 885, col. 1). Biotin can elicit an immune response, hence would be an immunologically active substance.

The reference does not specifically teach that the labeled UDP-GalNAc or UDP-Gal is capable of being transferred specifically to a surface of a pathogenic entity or malignant cell or tissue by a transferring enzyme making a covalent linkage between

Art Unit: 1642

said enzyme substrate and an acceptor structure, or transferred by a galactosyltransferase which is engineered to transfer effectively 2-modified monosaccharides or by a natural GalNAc/GlcNAc-transferase with similar specificity with said modified galactosyltransferase from animals, however, the claimed enzyme substrate appears to be the same as the prior art enzyme substrate, absent a showing of unobvious differences. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See *In re Best* 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Response to Arguments

7. Applicants argue that the Butler reference describes position 6-modified glycosyltransferase substrates and in contrast, the present 2-modified monosaccharide structures are clearly distinct from Butler. For a rejection to constitute "anticipation", all material elements of a claim must be found in the cited art reference. *In re Marshall*, 577 F.2d 301, 198 U.S.P.Q. 344 (CCPA 1978). Applicants argue that there exists no anticipation based upon Butler (p. 18).

The arguments have been considered but are not found persuasive because Bulter et al does teach a 2-modified monosaccharide. "Scheme 1" teaches R groups

attached to position 2 of the galactose monosaccharide in UDP-Gal or UDP-GalNAc, which would be a modification of the monosaccharide. Applicants appear to be arguing limitations not recited in the claims which are the attachment of the drug to the 2-position of the monosaccharide, however the claims broadly encompass any modification of the monosaccharide at the 2-position or any modification of the monosaccharide anywhere, therefore the enzyme substrate taught by Bulter et al anticipates the claimed substrate for the reasons of record.

8. **Claims 132, 134, 135, and 138 remain rejected under 35 U.S.C. 102(e)** as being anticipated by US Patent Application Publication 2004/0253651 (Saarinen et al, published Dec. 2004, filed August 2002) (see section 8 of the previous Office Action).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

The claims are drawn to as set forth above.

It is noted that the preamble recitation of "for use as a medicine" as recited in claim 132 is merely suggestive of an intended use and is not given weight for purposes of comparing the claims with the prior art. The claims read on the active ingredients *per se*, which is a composition comprising an enzyme substrate, wherein the enzyme

Art Unit: 1642

substrate is a 2-modified monosaccharide residue or the enzyme substrate is a modified monosaccharide residue (see MPEP 2111.02).

Saarinen et al teach a composition comprising an enzyme substrate UDP-GalN that can be transferred to an acceptor non-reducing end terminal GlcNAc or glucose using a glycosyltransferase ([0106]) or galactosyltransferase ([110]). UDP-GalN is a carbohydrate substance.

The reference does not specifically teach that the UDP-GalN is capable of being transferred specifically to a surface of a pathogenic entity or malignant cell or tissue by a transferring enzyme making a covalent linkage between said enzyme substrate and an acceptor structure, or transferred by a galactosyltransferase which is engineered to transfer effectively 2-modified monosaccharides or by a natural GalNAc/GlcNAc-transferase with similar specificity with said modified galactosyltransferase from animals, however, the claimed enzyme substrate appears to be the same as the prior art enzyme substrate, absent a showing of unobvious differences. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See *In re Best* 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Response to Arguments

9. Applicants argue that Saarinen et al. describe transfer of galactosamine, which is a monosaccharide, but not a modified monosaccharide as presently claimed. Therefore, there is no anticipation based upon Sarrinen et al (p. 18).

The arguments have been considered but are not found persuasive because Applicants appear to be arguing limitations not recited in the claims with regards to limiting what modifications occur to the monosaccharide. The claims are broadly drawn to a "modified monosaccharide residue" and Sarrinen et al teach UDP-GalN which encompasses the monosaccharide galactose that is modified by the addition of N and UDP, therefore the enzyme substrate taught by Sarrinen et al anticipates the claimed substrate for the reasons of record.

10. All other objections and rejections recited in the Office Action mailed September 9, 2009 are hereby withdrawn in view of amendments and arguments.

11. **Conclusion:** No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA B. GODDARD whose telephone number is (571)272-8788. The examiner can normally be reached on 7:00am-3:30pm.

Art Unit: 1642

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Laura B Goddard/
Primary Examiner, Art Unit 1642